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SERIAL NUMBER 877387, 219	FILING DATE 08/31/99	FIRST NAMED INVENTOR WALKER	ATTORNEY DOCKET NO. J P0074US1
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HM22/0131

EXAMINER

KISHORE, G

ART UNIT PAPER NUMBER

1615

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DATE MAILED: 01/31/01

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

☐ This application has been examined ☐ Responsive to communication filed on \_\_\_\_\_ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), \_\_\_\_\_ days from the date of this letter.  
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

**Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:**

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ \_\_\_\_\_

**Part II SUMMARY OF ACTION**

1. ☒ Claims 7-20 are pending in the application.

Of the above, claims \_\_\_\_\_ are withdrawn from consideration.

2. ☐ Claims \_\_\_\_\_ have been cancelled.
3. ☐ Claims \_\_\_\_\_ are allowed.
4. ☒ Claims 7-20 are rejected.
5. ☐ Claims \_\_\_\_\_ are objected to.
6. ☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on \_\_\_\_\_. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on \_\_\_\_\_, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed \_\_\_\_\_, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. \_\_\_\_\_; filed on \_\_\_\_\_.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

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### **DETAILED ACTION**

**The preliminary amendment filed on 8-31-99 is acknowledged.**

**Claims included in the prosecution are 7-20.**

#### ***Claim Rejections - 35 U.S.C. § 112***

- 1. The following is a quotation of the second paragraph of 35 U.S.C. 112:**

**The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.**

- 2. Claims 7-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

**Claim 7 lacks clarity. First of all, the mode of administration is unclear. Is it systemic or topical? What is meant by lipid substance? Does that mean the compound is a lipid? It is unclear what applicant intends to convey by the two limitations on lines 4-6; they appear to contradict each other. If the interaction between the therapeutic agent and the host environment is limited, then how can the agent be delivered? What is being conveyed by the terms, 'host environment' and 'in the host'? 'under conditions' is not a positive recitation in a method claim. These conditions should be specified. Similar is the case with claim 16 which also recites 'under conditions'.**

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***Claim Rejections - 35 U.S.C. § 102***

**3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:**

**A person shall be entitled to a patent unless --**

**(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.**

**4. Claims 7-10, 12, 14-15 rejected under 35 U.S.C. 102(e) as being anticipated by Keller (6,048,545).**

**Keller discloses a method of liposomal drug delivery using electric field. Keller teaches a variety of active agents encapsulated in the liposome and includes anti-cancer agents and nucleic acids Note the abstract, columns 3-6, examples and claims).**

***Claim Rejections - 35 U.S.C. § 103***

**5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:**

**(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.**

**6. Claims 9-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keller cited above.**

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**Keller does not give specific examples of the delivery of the claimed specific active agents. However, Keller teaches a variety of agents and provides guidance and it would have been obvious to one of ordinary skill in the art to deliver any drug based on Keller's teachings since the principle of delivery is the same.**

**7. Claims 7-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoffman (5,702,359) or Edwards (5,472,441) in combination with Keller cited above.**

**Hoffman discloses delivery of drugs using electrical fields. The device comprises electrodes including a satellite electrode (note the abstract, Figures, col. 1, and claims). What is lacking in Hoffman is the encapsulation of the drugs in liposomes.**

**Similarly Edwards discloses a treatment method in which the chemotherapeutic drugs are delivered to the site and by using a device containing electrodes (note the abstract, columns 1-5, Figures and claims). Although Edwards teaches encapsulation of the drugs, he does not specifically teach liposomes as the encapsulating agents (note col. 3, line 34 et seq.).**

**Keller as pointed out above, teaches the delivery of liposome encapsulated drugs using electrical fields. Furthermore, on col. 2, line 13 et seq., Keller discloses the advantages of using the liposome encapsulation of the drugs. It would have been obvious to one of ordinary skill in the art to use liposomes for the drug delivery taught by Hoffmann or Edwards because of the advantages of liposomes as carriers taught by Keller.**

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

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**Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.**



**Gollamudi S. Kishore, Ph. D**

**Primary Examiner**

**Group 1600**

*gsk*

**January 22, 2001**